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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,269	12/09/2005	Dorotea Raventos Segura	10496.204-US	8013

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NOVOZYMES NORTH AMERICA, INC.
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EXAMINER

NIEBAUER, RONALD T

ART UNIT	PAPER NUMBER
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1654

NOTIFICATION DATE	DELIVERY MODE
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09/17/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No. 10/560,269	Applicant(s) SEGURA ET AL.	
	Examiner RONALD T. NIEBAUER	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-49 is/are pending in the application.
- 4a) Of the above claim(s) 25-27 and 29-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24,28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants amendments and arguments filed on 5/26/09 and 10/2/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn. Briefly, the amendments and cancellation of claims have overcome the previous 112 2nd, 112 1st, 101,102, and 103 rejections. It is noted that claim 1 of the 3/3/08 claim set states that the 18th position (X17 of that claim set) could be Ala for example. Instant claim 24 excludes Ala from the 18th position. As such, the previously cited art (i.e. Hong et al) does not read on instant claim 24.

As noted in the interview summary dated 6/2/09 the requirement for a new sequence listing is withdrawn.

As noted in the previous office action, applicants elected species of SEQ ID NO:42 was found to be free of the prior art. There is no claim that reads solely on the elected species. The search was extended and other art was found that obviates claims as cited below. No claim is allowable. In accord with section 803.02 of the MPEP, the prior art search is not extended unnecessarily to cover all nonelected species. The examination has been extended to the extent to determine patentability. It is noted that instant claim 24 excludes Ala from position 18, while instant claim 36 includes Ala at position 18 and claim 36 also includes specific residues at position 19-21. The art cited below obviates claims 24,28 but does not obviate claim 36 for example.

Claims 1-23 have been cancelled.

Claims 34-35,48-49 are drawn to non-elected groups.

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Claims 34-35,48-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/3/08.

Claims 25-27,29-33,36-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/3/08.

Claims 24,28 are under consideration.

Claim Rejections - 35 USC § 103

This rejection is necessitated by applicants claim amendments.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24,28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tossi et al (Biopolymers (Peptide Science) v55 4-30 2000).

Tossi teach that alpha-helical antimicrobial peptides are a promising solution to the problem of microbial resistance (abstract). Tossi teach that numerous structure activity relationship studies have been performed aimed at improving activity and that such relationships are key to designing novel peptides (page 5 first column). In Figure 3, Tossi teach a comparison of over 150 peptides and teach that there is a significant positional conservation (page 16 last paragraph). Tossi state that the 20 residues of the sequence is generally essential and often sufficient for antimicrobial activity and is thus a reasonable basis for the design of short peptides (page 16-17 connecting sentence). Tossi teach that the distribution of residues is used to create a sequence template which is used to guide the design of peptides (page 16-17 connecting sentence).

Tossi does not expressly teach in a single embodiments the peptides of the instant invention.

Since Tossi teach that alpha-helical antimicrobial peptides are a promising solution to the problem of microbial resistance (abstract) one would be motivated to make such peptides. In the instant case, Tossi teach that numerous structure activity relationship studies have been performed aimed at improving activity and that such relationships are key to designing novel

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peptides (page 5 first column). Thus one would be motivated to design novel peptides. Since Tossi state that the 20 residues of the sequence is generally essential and often sufficient for antimicrobial activity and is thus a reasonable basis for the design of short peptides (page 16-17 connecting sentence) one would be motivated to make specific peptides as suggested by Tossi. Tossi teach that the distribution of residues is used to create a sequence template which is used to guide the design of peptides (page 16-17 connecting sentence, Figure 3). Based on figure 3 one would be motivated to use the most frequent residue at each of the 20 positions which is the peptide GLLSKLGKKAKKAGKGVRAKG. Since Tossi teach that the peptides are for addressing microbial resistance (abstract) one would be motivated to synthesize the peptides and prepare them in a composition to address the known problem in the art. Tossi teach methods of synthesizing peptides (page 26 first column) which is well-known in the art. Taken together, since Tossi motivate making the peptide GLLSKLGKKAKKAGKGVRAKG the limitations of claim 24 are met since GLLSKLGKKAKKAGKGVRAKG meets the structural limitations recited in claim 24. It is noted that claim 24 recites 'comprising the amino acid sequence', thus the peptide can include additional residues (see MPEP section 2111.03). Since Tossi recognize the peptides as antimicrobials and since GLLSKLGKKAKKAGKGVRAKG meet the structural limitations the peptide would have antimicrobial activity as recited in claim 24. Since Tossi teach that the peptides are for addressing microbial resistance (abstract) one would be motivated to synthesize the peptides and prepare them in a composition to address the known problem in the art. Thus the peptide would be present with a carrier during the synthesis process as recited in claim 28.

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In the instant case, one would be motivated to make the peptide GLLSKLGKKAKKAGKGVRAKG based on the express teachings and suggestions taught by Tossi as well as the problem in the art (i.e. microbial resistance). One would have a reasonable expectation of success since Tossi state that the 20 residues of the sequence is generally essential and often sufficient for antimicrobial activity and is thus a reasonable basis for the design of short peptides (page 16-17 connecting sentence).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference.

Conclusion

It is noted that claim 1 of the 3/3/08 claim set states that the 18th position (X17 of that claim set) could be Ala for example. Instant claim 24 excludes Ala from the 18th position. As such, the previously cited art (i.e. Hong et al) does not read on the instant claims. Thus applicants amendments have necessitated the new rejection. In accord with section 803.02 of the MPEP, this action is made final.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/

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Primary Examiner, Art Unit 1654

/Ronald T Niebauer/
Examiner, Art Unit 1654